VII. Robust Summaries of Data for Fatty Acid Dimers and Trimer

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, dimers
CAS #	61790-12-3
Remarks	This substance is also referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Dimer was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. The samples were then filtered (0.45 µm) if appropriate to remove undissolved material and allowed to sit overnight at ambient laboratory temperature. 100 ml of the clear supernatant/filtrate was obtained, the pH determined then adjusted to pH 2 with phosphoric acid. Samples were extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in tetrohydrofuran and assayed by gel permeation chromatography (GPC) using refractive index (RI) detection.
Results	The water solubility of dimer, in its entirety as a complex mixture, is < 0.12 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Dimer Acids and Related Products. Report No. 23763, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, trimers
CAS #	68937-90-6
Remarks	This substance is also referred to as trimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility

Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Trimer was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. The samples were then filtered (0.45 µm) if appropriate to remove undissolved material and allowed to sit overnight at ambient laboratory temperature. 100 ml of the clear supernatant/filtrate was obtained, the pH determined then adjusted to pH 2 with phosphoric acid. Samples were extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in tetrohydrofuran and assayed by gel permeation chromatography (GPC) using refractive index (RI) detection.
Results	The water solubility of trimer, in its entirety as a complex mixture, is < 0.37 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Dimer Acids and Related Products. Report No. 23763, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY

Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, dimers, hydrogenated
CAS #	68783-41-5
Remarks	This substance is also referred to as hydrogenated dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Hydrogenated dimer was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. The samples were then filtered (0.45 µm) if appropriate to remove undissolved material and allowed to sit overnight at ambient laboratory temperature. 100 ml of the clear supernatant/filtrate was obtained, the pH determined then adjusted to pH 2 with phosphoric acid. Samples were extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in tetrohydrofuran and assayed by gel permeation chromatography (GPC) using

	refractive index (RI) detection.
Results	The water solubility of hydrogenated dimer, in its entirety as a complex mixture, is < 0.52 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Dimer Acids and Related Products. Report No. 23763, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Fatty acids, C16 and C18-unsaturated, dimerized
CAS #	71808-39-4
Remarks	This substance is also referred to as crude dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Crude dimer was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. The samples were then filtered (0.45 µm) if appropriate to remove undissolved material and allowed to sit overnight at ambient laboratory temperature. 100 ml of the clear supernatant/filtrate was obtained, the pH determined then adjusted to pH 2 with phosphoric acid. Samples were extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in tetrohydrofuran and assayed by gel permeation chromatography (GPC) using refractive index (RI) detection.
Results	The water solubility of crude dimer, in its entirety as a complex mixture, is < 0.41 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Dimer Acids and Related Products. Report No. 23763, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, dimers
CAS #	61788-89-4
Remarks	This substance is also referred to as dimer in the Final Submission for Dimers and Trimer

Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Dimer and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, dimer had a partition coefficient range of 1.0 to 2.5.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M.and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Dimer Acids. Report No. 20979. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT

Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, trimer
CAS #	68937-90-6
Remarks	This substance is also referred to as trimer in the Final Submission for Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Trimer and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, trimer had a partition coefficient range of 2.2 to 8.9.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M.and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Dimer Acids. Report No. 20979. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT

Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, dimer, hydrogenated
CAS #	68783-41-5
Remarks	This substance is also referred to as hydrogenated dimer in the Final Submission for Dimers and Trimer

Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Hydrogenated dimer and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, hydrogenated dimer had a partition coefficient range of 0.7 to 6 .2.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M.and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Dimer Acids. Report No. 20979. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Fatty acids, C16 and C18-unsaturated, dimerized
CAS #	71808-39-4
Remarks	This substance is also referred to as crude dimer in the Final Submission for Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Crude dimer and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, crude dimer had a partition coefficient range of 2.4 to 7.5.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M.and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Dimer Acids. Report No. 20979. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301B "Ready Biodegradability: Modified Sturm Test."
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1991
Contact time	28 days
Inoculum	Activated sludge from a municipal sewage treatment plant
Test conditions	Inoculum: Activated sludge microorganisms were obtained from a municipal sewage treatment plant at Wateschap de Aa, Schijndel, the Netherlands. Concentration of test chemical: The test material was used at concentrations of 10 and 20 mg/L. Test Setup: Nutrient medium was prepared by adding 2 mL of a potassium phosphate solution, 1 mL each of magnesium sulfate, calcium chloride, and ammonium sulfate solutions, and 4 mL of a ferric chloride solution to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with the nutrient culture medium and 30 mL of inoculum and aerated over night. On day 1 of the study, the test and reference material (sodium benzoate, 20 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO_2 absorption bottles were connected in series to the exit air line of each bottle. CO_2-free air was bubbled through the solution. All experiments were performed at 20 to 22^{o}C. Sampling frequency: Samples were collected from the first CO_2 absorber vessel on days 2, 5, 7, 9, 12, 16, 21, and 28. Controls: Yes. Analysis: Samples from the CO_2 absorbers were analyzed using a Heraeus CHN-analyzer.
Results	
Degradation % after time	6.6% at 10 mg/L and 6.3% at 20 mg/L at 28 days (test article); 71% at 28 days (sodium benzoate).
Conclusions	The test article, at low and high concentrations, was degraded approximately 6% after 28 days and sodium benzoate was degraded 71% after 28 days. Under the conditions of the OECD guidelines, the test article was not readily biodegradable.

Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Coenen, T.M.M. 1991. Ready biodegradability: modified Sturm test. RCC NOTOX Project 052559. NOTOX, The Netherlands.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, trimers
CAS #	68937-90-6
Remarks	This substance is referred to as trimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B *Modified Sturm Test*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l. Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 51.31 mg of test material was weighed for direct addition to each appropriate bioreactor. Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and 54 mg of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, 53.9 mg of test item and 69 ml reference material stock. Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M $Ba(OH)_2$. At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 25, and 29. Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8. Calculation of Results: The weight of CO_2 evolved was calculated from the titre. The actual titre for each batch of

	$Ba(OH)_2$ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation: Weight CO_2 produced (mg) = 1.1 x (background titre – ml HCl titrated) The net CO_2 production was then calculated by subtracting the control mean CO_2 production from the test and reference material mean CO_2 production values. The percentage biodegradation was calculated by comparing actual CO_2 evolved in test and reference vessels with the theoretical CO_2 evolution. For the test item this was calculated using the DOC addition rate: $\% \text{ degradation} = \frac{\text{Mg } CO_2 \text{ produced}}{\text{mg DOC added} \times 3.67^{*}} \times 100$ * = where 3.67 is the conversion factor (44/12) for carbon to CO_2
Results Degradation % after time	11.1% after 28 days (trimer); 90.23% after 28 days (sodium benzoate)
Conclusions	Trimer was degraded 11.1 % after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Kelly, C.R. 2002. Fatty acids, C18-unsaturated, trimers, CAS No. 68937-90-6; Fatty acids, C18-unsaturated, dimers hydrogenated, CAS No. 68783-41-5; Fatty acids, C16-18 and C18 unsaturated, dimerized, CAS No. 71808-39-4. Determination of Ready Biodegradability of Three Dimer Acids by the Modified Sturm Test. Report No. 22016. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, C18-unsaturated, dimer, hydrogenated
CAS #	68783-41-5
Remarks	This substance is referred to as hydrogenated dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B *Modified Sturm Test*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from

	the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l. Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 51.31 mg of test material was weighed for direct addition to each appropriate bioreactor. Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and 54 mg of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, 53.9 mg of test item and 69 ml reference material stock. Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M $Ba(OH)_2$. At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 25, and 29. Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8. Calculation of Results: The weight of CO_2 evolved was calculated from the titre. The actual titre for each batch of $Ba(OH)_2$ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation: Weight CO_2 produced (mg) = 1.1 x (background titre – ml HCl titrated) The net CO_2 production was then calculated by subtracting the control mean CO_2 production from the test and reference material mean CO_2 production values. The percentage biodegradation was calculated by comparing actual CO_2 evolved in test and reference vessels with the theoretical CO_2 evolution. For the test item this was calculated using the DOC addition rate: $$\% \text{ degradation} = \frac{\text{Mg } CO_2 \text{ produced}}{\text{mg DOC added} \times 3.67^{*}} \times 100$$ * = where 3.67 is the conversion factor (44/12) for carbon to CO_2
Results Degradation % after time	9.46 % after 28 days (hydrogenated dimer); 68.18% after 28 days (sodium benzoate)
Conclusions	Hydrogenated dimer was degraded 9.46 % after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to

	be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Kelly, C.R. 2002. Fatty acids, C18-unsaturated, trimers, CAS No. 68937-90-6; Fatty acids, C18-unsaturated, dimers hydrogenated, CAS No. 68783-41-5; Fatty acids, C16-18 and C18 unsaturated, dimerized, CAS No. 71808-39-4. Determination of Ready Biodegradability of Three Dimer Acids by the Modified Sturm Test. Report No. 22016. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, C16 and C18-unsaturated, dimerized
CAS #	71808-39-4
Remarks	This substance is referred to as crude dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B *Modified Sturm Test*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l. Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 51.31 mg of test material was weighed for direct addition to each appropriate bioreactor. Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and 54 mg of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, 53.9 mg of test item and 69 ml reference material stock. Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M $Ba(OH)_2$. At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 25, and 29.

	Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8. Calculation of Results: The weight of CO_2 evolved was calculated from the titre. The actual titre for each batch of $Ba(OH)_2$ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation: Weight CO_2 produced (mg) = 1.1 x (background titre – ml HCl titrated) The net CO_2 production was then calculated by subtracting the control mean CO_2 production from the test and reference material mean CO_2 production values. The percentage biodegradation was calculated by comparing actual CO_2 evolved in test and reference vessels with the theoretical CO_2 evolution. For the test item this was calculated using the DOC addition rate: $$\% \text{ degradation} = \frac{\text{Mg } CO_2 \text{ produced}}{\text{mg DOC added} \times 3.67^{*}} \times 100$$ * = where 3.67 is the conversion factor (44/12) for carbon to CO_2
Results Degradation % after time	29.29 % after 28 days (crude dimer); 90.23 % after 28 days (sodium benzoate)
Conclusions	Crude dimer was degraded 29.29 % after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Kelly, C.R. 2002. Fatty acids, C18-unsaturated, trimers, CAS No. 68937-90-6; Fatty acids, C18-unsaturated, dimers hydrogenated, CAS No. 68783-41-5; Fatty acids, C16-18 and C18 unsaturated, dimerized, CAS No. 71808-39-4. Determination of Ready Biodegradability of Three Dimer Acids by the Modified Sturm Test. Report No. 22016. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ACUTE TOXICITY TO FISH	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated, dimer
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test"* and following procedures in OECD (2000) Series on Testing and Assessment, No. 23, *"Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures."*
Year	2002
GLP (Y/N)	Y

System of testing	Fathead minnows (*Pimephales promelas)* under static conditions.
Concentration	0, 1, 10, 100 and 1000 mg/l
Results	The 96 hr LL_{50} was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Detailed Summary	Dimer was tested in fathead minnows under static conditions to determine the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of the test substance were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test using the highest loading rate (i.e., 1000 mg/l). Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 96 hr LL_{50} was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Kelly, C. 2002. Fatty acids, C18-Unsaturated dimers, CAS No. 8050-26-8 Determination of Acute Toxicity (LL_{50}) to Fathead Minnows (96 h, Static). Report Number 20785. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated, dimer
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"* and following procedures in OECD (2000) Series on Testing and Assessment, No. 23, *"Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures.""*
Year	2002
GLP (Y/N)	Y
System of testing	*Daphnia magna* (water fleas) under static conditions.
Concentration	0, 1, 10, 100 and 1000 mg/l
Results	The 48 hr LL_{50} was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Detailed Summary	Dimer was tested in daphnia under static conditions to determine

	the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of the test substance were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test using the highest loading rate (i.e., 1000 mg/l). Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 48 hr LL_{50} was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Kelly, C. 2002. Fatty acids, C18-Unsaturated dimers, CAS No. 61788-89-4 Determination of Acute Toxicity (LL_{50}) to *Daphnia* (48 h, Static). Report Number 21050. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ALGA, GROWTH INHIBITION	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated, dimer
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	OECD Test Method 201, *"Testing of Chemicals, Alga, Growrh Inhibition Test"* and following procedures in OECD (2000) Series on Testing and Assessment, No. 23, *"Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures."*
Year	2002
GLP (Y/N)	Y
System of testing	Green alga (*Selenastrum capriconutum)* growth inhibition.
Concentration	0, 1, 10, 100 and 1000 mg/l
Results	The 72 hr EL_{50} for area under growth curve (AUC) and Average Specific Growth Rate (0-72h) was > 1000 mg/l. The No Observed Effect Loading Rate ($NOEL_r$) for Average Specific Growth Rate and AUC was 1000 mg/l.
Detailed Summary	Dimer was tested in alga to determine the median effective loading (EL_{50}) for growth inhibition. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of the test substance were added to a stirring medium in glass vessels which were sealed to avoid loss

	of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test using the highest loading rate (i.e., 1000 mg/l). Because there was no inhibition of algal growth in the range finding test in any test groups, a definitive test was conducted at 1000 mg/l with algal cell concentrations recorded after 1, 24, 48 and 76 hrs. This test was conducted using an unfiltered WAF with no pH adjustment. As no effects or inhibition was observed the 72 hr EL_{50} was > 1000 mg/l for area under growth curve (AUC) and Average Specific Growth Rate (0-72h). Consequently, the No Observed Effect Loading Rate ($NOEL_r$) for AUC and Average Specific Growth Rate is 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Kelly, C. 2002. Fatty acids, C18-Unsaturated dimers, CAS No. 61788-89-4 Alga, Growth Inhibition Test (72 h, EL_{50}). Report Number 20966. Inveresk Research, Tranent, Scotland.

ACUTE TOXICITY – ORAL

Test substance

Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer

Method

Method/Guideline followed	Testing was conducted according to OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1986
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	5,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N

Result

Acute Oral LD_{50}	>5,000 mg/kg
Detailed Summary	Wistar rats (n = 5/sex) received a single oral dose of 5000 mg/kg of dimer (CAS #61788-89-4) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. No effects on mortality, clinical

	signs or body weight were reported. Gross necropsy revealed no treatment-related effects. The acute oral LD_{50} was greater than 5000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Thouin, M.H. 1986. Evaluation of acute oral toxicity of [trade name deleted; dimer] in the rat. NOTOX 0336/416. NOTOX, The Netherlands.

ACUTE TOXICITY – ORAL

Test substance

Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer

Method

Method/Guideline followed	Testing was conducted according to OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1989
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	2,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N

Result

Acute Oral LD_{50}	>2,000 mg/kg
Detailed Summary	Sprague-Dawley rats (n = 5/sex) received a single oral dose of 2000 mg/kg of dimer (CAS #61788-89-4) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. No mortalities occurred and no changes in clinical signs, body weight or gross pathology were reported. The acute oral LD_{50} was greater than 2000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Saboureau, D. 1989. Evaluation of the acute toxicity in the rat by the oral route. TAO 88.1518. Biogir S.A. Conseil Recherche, France.

ACUTE TOXICITY – ORAL

Test substance

Chemical Name	Fatty acids, C18-unsaturated dimers, hydrogenated
CAS #	68783-41-5
Remarks	This substance is referred to as hydrogenated dimer in the Final Submission for Fatty Acid Dimers and Trimer

Method

Method/Guideline followed	Test procedure was consistent with OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	Y
Year (Study Performed)	1988
Species	Rat
Strain	Wistar
Route of administration	Oral
Dose levels	5,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N

Result

Acute Oral LD_{50}	>5,000 mg/kg
Detailed Summary	Wistar rats (n = 5/sex) received a single oral dose of 5000 mg/kg of hydrogenated dimer (CAS #68783-41-5) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. Mortality, clinical signs, body weight, and gross pathology were unaffected by treatment. The acute oral LD_{50} was greater than 5000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Reijnders, J.B.J. 1988. Acute oral toxicity of [trade name deleted; hydrogenated dimers] in the rat. RCC NOTOX 0811/1041. NOTOX, The Netherlands.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 408, "Subchronic Oral Toxicity – Rodent: 90-Day."
Year	1993
GLP (Y/N)	Y
Species	Rat
Strain	Sprague-Dawley
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	13 weeks
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0.1, 1, 5%
Control group (Y/N)	Y
Results	
NOAEL:	0.1%
Detailed Summary	Dimer (CAS #61788-89-4) was administered to CD Sprague-Dawley rats (n = 20/sex/group) in the diet at concentrations of 0, 0.1, 1, or 5% for 13 weeks. The approximate doses were 0, 100, 1,000, or 5,000 mg/kg/day, based on standard conversion factors (WHO 1990). Parameters evaluated included clinical signs, body weight, food and water consumption, ophthalmoscopy, hematology, clinical chemistry, gross pathology, organ weights (brain, heart, liver, kidneys, spleen, testes, adrenal glands), and microscopic pathology (adrenal glands, brain, colon, femur and stifle joint, ileum, larynx, lymph nodes, muscle, ovaries and fallopian tubes, pituitary, sciatic nerve, sternum, thyroid and parathyroids, uterus, aorta, cecum, duodenum, head, jejunum, liver, esophagus, pancreas, prostate, spinal cord, stomach, tongue, bladder, cervix, heart, kidneys, lungs, mammary glands, rectum, spleen, thumus, trachea, epididymides, skin, salivary glands, testes, seminal vesicles, vagina, eyes/harderian glands). No deaths occurred and no treatment-related effects on clinical signs, body weight, body weight gain, water intake, or ophthalmoscopy were noted. A transient, statistically significantly decrease in food consumption occurred in the 5% males and females during the first four weeks of study. The animals exhibited normal consumption from week 4 through 13. Slight changes in hemoglobin (increased in 5% males) and prothrombin time (increased in 1% females and 5% males and females) were considered not to be toxicologically significant. Treatment-related clinical chemistry changes included statistically significant increases in alkaline phosphatase (1 and 5% males and females) and ALT (5% males and females), and statistically significant decreases in total cholesterol (1 and 5% males and females), triglycerides (1% males and 5% males and females), total serum

	protein and albumin (5% males and females), and beta-globulin fraction (1 and 5% males). At necropsy, the mesenteric lymph nodes were slightly to moderately enlarged in all dimer treatment groups and the incidence of uterine fluid distension was increased at 5%. Absolute and relative spleen (males at 1 and 5%) and liver (males and/or females at 1 and 5%) weights were statistically significantly decreased. In addition, absolute kidney weight was significantly decreased in females at 5% and absolute and relative liver weights were significantly decreased in females at 0.1%. The relevance of these decreases in organ weights is not known, since they did not correlate to any microscopic changes. Histopathology revealed treatment-related findings in the following organs: mesenteric lymph nodes (aggregation of macrophages in both sexes at 0.1% and higher); spleen (macrophages with brown pigment in both sexes at 1 and 5% and in the females at 0.1%); liver (bile duct proliferation and bile duct sclerosis in males at 5%); adrenals (cortical vacuolation in females at 1 and 5%); and thyroids (follicular epithelial hypertrophy in females at 5%). Although a no-effect-level was not identified in this study, 0.1% (approximately 100 mg/kg/day) can be considered a no-observed-adverse-effect-level based on increases in clinical chemistry parameters and histopathological findings at the higher doses.
Data Quality	Valid without restriction – Klimisch Code 1a
References	Spurgeon, M., and Hepburn, P. 1993. Dimer acid: 13 week feed study in the rats. Study FT920485. Environmental Safety Laboratory, England. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPRODUCTIVE/DEVELOPMENTAL TOXICITY SCREENING TEST	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	OECD Test Guideline 421, *"Reproduction/Developmental Toxicity Screening Test."*
GLP (Y/N)	Y
Year (Study Performed)	2003
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral via diet
Dose levels	0, 200, 2000 and 20,000 ppm
Sex and number/group	40 males and 40 females
Frequency of treatment	Males were treated for at least 4 weeks overall, starting from 2 weeks prior to mating until termination; females were treated for 2 weeks prior to mating, then through mating until termination after Day 4 of lactation.

Duration of test	4 weeks
Control group (Y/N)	Y
Result	
Parental NOEL Reproductive/developmental NOEL	2000 ppm (approximately 180 mg/kg/day) 20,000 ppm (approximately 1858 mg/kg/day)
Detailed Summary	Four groups of 10 male and 10 female Sprague-Dawley rats received the dimer *via* the diet at concentrations of 0, 200, 2000 and 20,000 ppm. The males were dosed for at least 4 weeks, starting from 2 weeks prior to mating. The females were dosed from 2 weeks prior to mating until at least Day 6 of lactation. The animals were monitored for clinical signs, body weight, food consumption, mating and litter performance. All animals were submitted for necropsy, which included weighing male reproductive organs. Histopathology was conducted on the epididymides and testes of all control and high dose males and on the ovaries of all control and high dose females. Paternal toxicity was exhibited at 20000 ppm as a slight decrease in weight gain and an increase in piloerection. There were no obvious maternal effects at this level. There were no obvious parental effects at 200 or 2000 ppm, nor were there any effects of treatment on the reproductive parameters at any dose level applied. The testes and epididymides weights were essentially similar in all groups. The mean number of implants per pregnancy was higher in all the treated groups compared to controls. However, historical data shows that the findings in the treated groups were within background ranges for animals of this age and strain. Rather, it was considered most likely that the control value was at the lower end of the background range. There were no obvious effects of treatment on litter size, litter survival, or pup weights at any dose level and no abnormalities noted among pups. Under the conditions of this study, the parental No Observed Effect Level (NOEL) was considered to be 2000 ppm (approximately 180 mg/kg/day) and for reproductive parameters the NOEL was considered to be 20000 ppm (approximately 1858 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Clubb, S. 2003. Dimer (CAS No. 61788-89-4) Reproduction/Developmental Toxicity Screening Test. Report Number 22828. Inveresk Research, Tranent, Scotland.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD method # 471, "Bacterial Reverse Mutation Assay"
Year	2000
GLP (Y/N)	Yes
System of testing	*S. typhimurium* strains TA98, TA100, TA 102, TA1535, TA1537
Concentrations	33, 100, 333, 1000, 2500 and 5000 μg/plate
Metabolic activation	With and without S9
Results	Non-mutagenic
Detailed Summary	An Ames test was conducted in *S. typhimurium* strains TA98, TA100, TA 102, TA1535, and TA1537. Dimer (CAS #61788-89-4) concentrations of 33, 100, 333, 1000, 2500 and 5000 μg/plate were tested with and without metabolic activation (S9 mix). No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with dimer at any concentration level either in the presence or absence of metabolic activation (S9 mix). Thus, dimer was not considered to be mutagenic.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Wollny, H. 2000. Salmonella Typhimurium assay with [trade name deleted; dimers] RCC Cytotest Cell Research, GMBH, Robdorf.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 476, "*In vitro* Mammalian Cell Gene Test."
Year	1993
GLP (Y/N)	Y
System of testing	Mouse lymphoma L5178Y cells
Concentration	25 to 300 µg/mL
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Dimer (CAS #61788-89-4) was incubated *in vitro* with L5178Y mouse lymphoma cells for three hours at concentrations ranging from 25 to 300 µg/mL with and without metabolic activation (S9 mix). Samples were collected at 24 and 48 hours to assess growth. After 48 hours, cells were collected, plated, and incubated for 12 days to assess viability and mutant frequency. The assay was conducted in duplicate. In Test 1 (without S9), toxicity was observed at 300 µg/mL and in Test 2 (without S9) toxicity was observed at 275 and 300 µg/mL. These concentrations were excluded from the mutation analyses. A statistically significant increase in mutant frequency was observed in Test 2 at 250 µg/mL. However, because the increase was small, it was not considered biologically significant; no increase occurred in Test 1. Tests 1 and 2 (with S9 mix) produced reduced survival at 300 µg/mL and 250 µg/mL and above, respectively. These concentrations were excluded from the mutation analyses. No increase in mutant frequency was observed. Dimer acid did not demonstrate mutagenic potential in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Adams, K. 1993. Dimer acid: mouse lymphoma TK locus assay. ULR 472/930202. Huntingdon Research Centre Ltd., England.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C18-unsaturated dimers
CAS #	61788-89-4
Remarks	This substance is referred to as dimer in the Final Submission for Fatty Acid Dimers and Trimer
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 473, "*In Vitro* Mammalian Cytogenetic Test."
Year	1993
GLP (Y/N)	Y
System of testing	Human lymphocytes
Concentration	9.4 to 300 µg/mL
Metabolic activation	With and without
Results	Non-mutagenic
Detailed Summary	Human lymphocytes were incubated with dimer (CAS #61788-89-4) at concentrations ranging from 75 to 300 µg/mL with and without metabolic activation. In the first assay, the cultures containing S9 mix were centrifuged three hours after dosing and fresh medium was added for an additional 15 hours. In the second assay, half the cultures were processed following the procedure used in the first assay with a harvest at 18 hours and the other half were harvested at 32 hours. For all tests, two hours prior to treatment cessation, mitotic activity was arrested by the addition of colchicine, and the number of mitotic cells per 1000 cells in each culture was determined microscopically. No significant increase in the proportion of aberrant cells was observed in either the first or second assay with or without metabolic activation. Dimer demonstrated no clastogenic activity in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Akhurst, L. 1993. Dimer acid: metaphase chromosome analysis of human lymphocytes cultured *in vitro*. ULR 471/930241. Huntingdon Research Centre Ltd., England.